REMARKS

Claims 1, 3 and 5-9 are now in the case.

Claims 2 and 4 have been canceled.

Claims 1, 3 and 5-9 are rejected.

No claim has been allowed.

The Amendments.

Independent Claim 1 has been limited to the deposit strain of *F. columnare* previously recited in dependent Claims 2 and 4, now both canceled. Claim 7 has been amended to correct an informality identified by the Examiner.

Claim Objection Maintained, Claim 7.

Claim 7 has been objected to a second time for starting with an improper article. Applicants' failure to correct this problem in the previous response was an oversight. Claim 7 has now been amended to begin with the article "The".

New Objections.

The amendment filed on March 21, 2005, has been objected to under 35 U.S.C. §132(a) as introducing new

matter into the disclosure. The Examiner maintains that the term "CFU/mL" introduced twice in Paragraph **[0023]** does not appear to have support in the specification. Applicants respectfully refute the Examiner's position and request withdrawal of the objection for the reasons that follow.

Paragraph **[0023]** describes an *in vivo* adhesion assay based on a plate count using tissue from dead fish which had previously been immersion-exposed to virulent *F. columnare* strain ARS-FC1-96 and to mutant *F. columnare* strain NRRL B-30687. Though the numerical levels (10^6) of exposure were specified, the units (CFU/mL) were inadvertently omitted from the passage at issue. A very similar protocol involving immersion challenge, but at the 10^8 CFU/mL level, is described in paragraph **[0025]**. Likewise, Example 2 (paragraph **[0027]** describes an immersion challenge using vaccine strain NRRL B-30687 at concentrations of 1.5×10^8 CFU/mL. Similarly, the efficacy studies described in Examples 3 show that the treatment levels of 3×10^7 (para. **[0031]**) and 5×10^6 (para. **[0034]**) were in units of CFU/mL. Applicants submit that these several references to the units of the treatment agent provide adequate support for the CFU/mL in paragraph **[0023]**.

The Rejection of Claims 2 and 4 under 35 U.S.C. §112, First Paragraph.

Claims 2 and 4 stand rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is based on Applicants' alleged failure to fully comply with the requirements for the future availability of the deposit strain NRRL B-30687. **The reason why this rejection has been maintained is not understood.** Withdrawal of this rejection is respectfully requested.

As pointed out in Paragraph **[0009]** of the specification, the claimed strain has been deposited under the conditions of the **Budapest Treaty** in the Agricultural Research Service Culture Collection (NRRL) in Peoria, Illinois, and has been assigned Accession No. NRRL B-30687. In the previous response, Applicants made the statement over the signature of the agent of record that **UPON THE ISSUANCE OF A PATENT, ALL RESTRICTIONS ON THE AVAILABILTY OF NRRL B-30687 WILL BE IRREVOCABLY REMOVED WITHOUT RESTRICTION OR CONDITION.** The Examiner points out that in

the first paragraph on page 4 of the Office Action that such a statement satisfies the deposit requirements for a deposit under the Budapest Treaty (37 CFR 1.808). Moreover, the identifying information for the deposit strain has been given in the specification. The characteristics of the deposit strain have been described in terms of its smooth-edged morphology as compared to the parent strain ARS-FC1-96 (para. **[0018]**). At the top of page 13, Applicants state that the biochemical characteristics of NRRL B-30687 were identical to the parent strain. Moreover, the deposit strain was further characterized as producing less of both a 40 kDa protein and a 50 kDa protein than the parent strain (para. **[0020]**) and as adhering significantly less than the parent strain (para. **[0022]**).

If there is some specific deposit requirement that Applicants have failed to meet, the Examiner is asked to specifically point it out so that the record can be immediately remedied.

The Rejection of Claims 1, 3 and 5-9 under 35 U.S.C. §112, First Paragraph.

Claims 1, 3 and 5-9 stand rejected under 35 U.S.C. §112, first paragraph, because the specification, while

being enabling for an attenuated, ampicillin resistant *Flavobacterium columnare* which is effective for eliciting a protective immune response in fish against virulent strains of *F. columnare* wherein the protective bacterium is strain NRRL B-30687, does not provide enablement for any other attenuated strain of *Flavobacterium* or their use as a vaccine against virulent strains of *Flavobacterium* in fish. The Examiner states that the specification does not enable any person skilled in the art to make and use the invention commensurate in scope with these claims. Withdrawal of this rejection is requested for the reasons that follow.

Independent Claim 1 is now limited to deposit stain NRRL B-30687 of *F. columnare* which has been demonstrated as being effective for eliciting an immune response in fish, which immune response is protective against infection by virulent strains of *F. columnare*. This strain is characterized by smooth-edged colonies having significantly less ability to adhere to skin tissue than the parent, non-attenuated strain. Given that Claims 2 and 4 were not included in this rejection, it is presumed that all claims are now free of the rejection.

The Rejection under 35 U.S.C. §112, Second Paragraph.

Claim 1-9 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner states that Claim 1 is rendered vague and indefinite by the use of the phrase "significantly less ability to adhere to skin tissue than the parent…" in that this phrase is not explicitly defined in the specification. Withdrawal of this rejection is requested.

Applicants have clearly defined "significantly" in the specification as meaning $P \leq 0.05$ (paragraphs **[0022]** and **[0024]**). Given that the claims are to be read in light of the disclosure, Applicants submit that the meaning of the expression is clear.

Summary.

Applicants have amended Claim 1 to positively recite the deposit strain and have amended Claim 7 to remove the ambiguity regarding the opening article. Given that the deposit strain was previously recited in dependent Claims 2 and 4, no new issues are deemed to have been raised.

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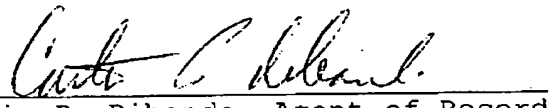
As noted above in Applicants' remarks, all issues under 35 U.S.C. §112, first and second paragraphs and the issue of new matter are all believed to have been resolved. The claims are free of the prior art.

Accordingly, Claims 1, 3 and 5-9 are deemed to be in condition for allowance, and a favorable action thereon is earnestly solicited. **If the Examiner believes that there are any issues that need to be addressed before allowance of the application, he is invited to call the undersigned at 309-681-6512.**

Respectfully submitted,



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